REMARKS

Claims 6 and 7 are pending in this application. Claims 6 and 7 have been rejected. Claims 6 and 7 have been canceled. Claims 8 and 9 have been added. No new matter has been added by this amendment. Applicants are respectfully requesting reconsideration in light of the amendments to the claims and the following remarks.

I. Claim Interpretation.

At pages 2-3 of the Office Action, the Examiner asserts that the transitional phrase "of" allows for the inclusion of outside elements, such that any prior art reference disclosing a product, isolated in any manner from its natural surroundings, that necessarily contains the recited "fraction" would read on the claimed invention.

Applicants respectfully disagree. However, in the interest of clarifying the nature of the composition of this invention, Applicants have canceled claims 6-7 and added new claims 8-9, which particularly refer to the claimed composition as a well characterized, isolated mammalian RNA fraction. Support for this amendment is found in the claims as previously presented and at pages 4-8 of the Specification.

II. Rejection of Claims Under 35 U.S.C. 112

Claims 6-7 remain rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement. It is suggested that the claimed invention encompasses fractions of nucleic acid molecules that are not described in the specification in such a way as to convey to one skilled in the art that the inventors had possession of

the claimed genus. In particular, it is suggested that the specification provides no support for fractions of strictly polyA- RNA molecules greater than 400, 500 etc. nucleotides that enhance amplification of PrP^{Sc}. The Examiner contends that Applicants have isolated a fraction of molecules which enhance amplification of PrP^{Sc}, but have yet to elucidate the actual sequence structure of the specific molecule within the fraction that are responsible for the amplification. The Examiner concludes that the disclosure does not describe a composition wherein every single molecule with that composition possesses the claimed characteristics.

Applicants respectfully disagree with this rejection. At the outset, Applicants respectfully point out that claims 6-7 have been canceled and new claims 8-9 have been presented to clarify the nature of the claimed composition. As the Examiner has acknowledged at page 6, ¶1 of the Office Action, Applicants have isolated a fraction of molecules which enhance amplification of PrP^{Sc}. As described in the passage spanning page 4 (line 25) and page 5 (line 17), amplification of PrP^{Sc} was sensitive to degradation by DNase-free pancreatic RNase, RNase A, and RNase T1, but resistant to degradation by RNase V1, RNaseH, *Eco*RI, apyrase, heparinase, and DNase. Accordingly, Applicants concluded that amplification of PrP^{Sc} was RNA-mediated. Thus, Applicants obtained isolated RNA from brain tissue and determined that the amplification of PrP^{Sc} was mediated by an RNA fraction that did not bind to an oligo dT column and contained RNA of greater than 300 nucleotides as determined by ultrafiltration (page 7, lines 3-22 of the Specification). Moreover, the RNA-mediated amplification of

PrP^{Sc} was identified as being specific to mammals (see page 8, lines 8-23, and page 9, lines 25-32 of the Specification). Given this disclosure, persons of skill in the art would have recognized that, at the time of filing of the Application, Applicants were in possession of the isolated mammalian RNA fraction as characterized in claims 8 and 9. *Vas-Cath*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

The Examiner has cited *Eli Lilly* in support of this rejection. However, Applicants respectfully assert that *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what was claimed. While describing the complete chemical structure, *i.e.*, the nucleotide sequence of a claimed molecule is one method of satisfying the written description requirement, it is not the only method. *See Eli Lilly,* 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA *** requires a precise definition, *such as* by structure formula, chemical name, or physical properties." [emphasis added, internal quote omitted]). Therefore there is no basis for a *per se* rule requiring disclosure of complete nucleotide sequences. See page 1101, paragraph spanning col. 2 and 3 of the Federal Register, Vol. 66, No. 4 (Jan. 5, 2001).

Applicants have provided a number of physical characteristics of the claimed composition that are fully supported by disclosure and convey to one skilled in the art in a conventional and well understood manner, that Applicants had possession of the invention as presently claimed. Accordingly, the written description requirement under 35 U.S.C. §112, first paragraph, has been met. It is

therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Rejection of Claims Under 35 U.S.C. 102

Claim 6 remains rejected under 35 U.S.C. 102(b) as being anticipated by Saborio et al. ((2001) *Nature* 411:810-3). The Examiner contends that this reference teaches a composition comprising a fraction of polyA- RNA molecules greater than 300 nucleotides that enhances the amplification of PrP^{Sc}, asserting that healthy hamster brain homogenate necessarily "comprises" a fraction of polyA- RNA greater than 300 nucleotides that enhance the amplification of PrP^{Sc}. Applicants respectfully traverse this rejection.

In so far as claims 6 and 7 have been canceled, the prior art rejections will be addressed with respect to the subject matter as presented in new claims 8 and 9.

Saborio et al. teach total hamster brain homogenate for amplifying PrP^{Sc}. However, this reference does not teach or suggest an isolated mammalian RNA fraction possessing the characteristics as presently claimed. MPEP 2131. Therefore, this reference cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection be withdrawn.

Claim 6 remains rejected under 35 U.S.C. 102(b) as being anticipated by Mizutani et al. ((2000) *Virology* 275:238-43). It is suggested that this reference teaches the isolation of mouse polyA- RNA molecules from total RNA and subsequent gel separation. The Examiner contends that the combination of gel fractions of Mizutani et al. containing RNA molecules greater than 300 nucleotides necessarily

enhances the amplification of PrP^{Sc}. Applicants respectfully traverse this rejection.

To anticipate, a reference must clearly and unequivocally disclose the claimed invention. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972).

While the Examiner has referenced the teachings at page 239, col. 1 of Mizutani et al. in support of this rejection, Applicants respectfully point out that this passage teaches isolation of RNA from DBT cells infected with MHV. In so far as cultured cells are not under the same environmental conditions as cells *in vivo* (*i.e.*, in brain tissue), one skilled in the art would appreciated that the transcriptome of cultured cells is not the same as that of cells *in vivo*. Therefore, it is scientifically and legally improper to conclude that the RNA fraction of Mizutani et al. anticipates an isolated mammalian RNA fraction from brain tissue as presently claimed. As such, this reference cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection under 35 U.S.C. 102(b) be withdrawn.

IV. Rejection of Claims Under 35 U.S.C. 103

Claim 7 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Saborio et al. or Mizutani et al. in view of Stratagene ("Gene Characterization Kits" 1988). It is suggested that it would have been obvious, based upon the supportive teaching of the Stratagene catalog, to combine reagents into kit format. Applicants respectfully traverse this rejection.

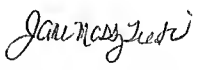
As Applicants pointed out in reply to the rejection of claim 6 in view of Saborio et al., this reference fails to

teach or suggest an isolated mammalian RNA fraction possessing the characteristics as presently claimed. Accordingly, the combination of the references would not replicate the claimed invention, because the combined teachings of the cited references fail to teach each and every limitation of the claimed invention. Therefore, the combined teachings of the cited references cannot be held to make the present invention obvious and it is respectfully requested that this rejection be reconsidered and withdrawn.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claim is earnestly solicited.

Respectfully submitted,



Jane Massey Licata
Registration No. 32,257

Date: **March 1, 2010**

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515
Email: jmlicata@licataandtyrrell.com